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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/938,671	08/27/2001	David W. LaFleur	PZ022P1C2	3552

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EXAMINER	
WHISENANT, ETHAN C	

ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 01/12/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/938,671	LAFLEUR ET AL.	
	Examiner	Art Unit	
	Ethan Whisenant, Ph.D.	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 October 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,11,13-15,17-20,22 and 24-51* is/are pending in the application.

4a) Of the above claim(s) *11,13,15,17-20,22 and 24* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 25-33, 37, and 40-51* is/are rejected.

7)☐ Claim(s) *14,34-36,38 and 39* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

NON-FINAL ACTION

1. The applicant's election of Group I with traverse in paper filed 22 OCT 03 is acknowledged. Following the entry of the Claim amendments Claim(s) 1, 11, 13-15, 17-20, 22, and 24-51 are pending. Please note that Claim(s) 11, 13, 15, 17-20, 22 and 24, are withdrawn from further consideration as being directed toward a non-elected invention. The claims currently being prosecuted are **Claim(s) 1, 14, 25-51.**

The traversal of the restriction requirement is based on the applicant's contention that it is not a burden on the examiner to search Groups I-X together. The applicant's argument has been fully considered but is not deemed to be persuasive. A *prima facie* case of burden has been shown because the inventions have acquired a separate status in the art as shown by their different classification. Because the restriction requirement is deemed proper it is herein made **FINAL**.

►As regards rejoinder the examiner will consider such request once an allowable product claim is found.

►Please note that in the analysis which follows, the phrase SEQ ID NO:X has been limited to SEQ ID NO:38 while SEQ ID NO: Y has been limited to SEQ ID NO: 83 and ATCC Deposit No: Z has been limited to ATCC Deposit No: 209563.

SEQUENCE RULES

2. This application complies with the sequence rules and the sequences have been entered by the Scientific and Technical Information Center.

CLAIM OBJECTIONS

3. **Claim(s) 14, 34-36, 38-39** is/are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. As regards Claim 14, please note that Claim 11 has been withdrawn as it is directed toward a non-elected invention. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form.

Accordingly, these claims has not been further treated on the merits. As regards Claims 34-35, 38-39, using the claim form like that form used in Claims 30-32 would overcome these objections.

35 USC § 101

4. 35 U.S.C. § 101 reads as follows:

> "Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title".

Claim Rejections - 35 USC § 101

5. **Claim(s) 1, 25-33, 37, 40-51** is/are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific or substantial asserted utility or a well established utility.

35 USC § 112 - 1st Paragraph

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

CLAIM REJECTIONS under 35 USC § 112- 1ST PARAGRAPH

7. **Claim(s) 1, 25-33, 37, 40-51** is/are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific or substantial asserted utility or a well established utility one skilled in the art clearly would not know how to use the claimed invention.

35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that may form the basis for rejections set forth in this Office action:

> A person shall be entitled to a patent unless –
>
> **(a)** the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> **(b)** the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> **(e)** The invention was described in –
> (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or
> (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a)

►Please note that the following prior art rejections are made in view of the very broad scope encompassed by pending claims.

CLAIM REJECTIONS UNDER 35 USC § 102

9. **Claim(s) 1, 33, 37** is/are rejected under 35 U.S.C. 102(b) as being anticipated by Sommer et al.(1989).

Claim 1 is drawn to an isolated nucleic acid molecule comprising a polyucleotide having a nucleotide sequence at least 95% identical to a sequence selected from a defined group which include a polynucleotide fragment of SEQ ID NO: 38 or a polyucleotide fragment of the cDNA sequence included in ATCC Deposit No: 209563, which is hybridizable to SEQ ID NO: 38.

Sommer et al. teach a an isolated nucleic acid molecule comprising a polyucleotide (i.e. primer : 5'- TCGCAACATCGCAGCTA –3', see first primer listed Table I) having (i.e. comprising) a nucleotide sequence (5' – GCTA – 3') that is at least 95% identical to a polynucleotide fragment of SEQ ID NO: 38. Note, for example, that the sequence 5' – GCTA – 3' in the primer taught by Sommer is 100% identical to nucleotides 909-912 of SEQ ID NO: 38.

In addition, **Claim 1** is drawn to an isolated nucleic acid molecule comprising a polyucleotide having a nucleotide sequence at least 95% identical to a sequence selected from a defined group which include a polynucleotide encoding SEQ ID NO: 83 or a polypeptide fragment of SEQ ID NO: 83 or a polypeptide fragment encoded by the CDNA sequence included in ATCC Deposit No: 209563, which is hybridizable to SEQ ID NO: 38.

Sommer et al. teach an isolated nucleic acid molecule comprising a polyucleotide (i.e. primer : 5'-TCGCAACATCGCAGCTA –3', see first primer listed Table I) having (i.e. comprising) a nucleotide sequence (5' – GCTA – 3') that is at least 95% identical to a polynucleotide encoding SEQ ID NO: 83 (i.e. SEQ ID NO:38), or a polynucleotide fragment of SEQ ID NO: 38. Note, for example, that the sequence 5' – GCTA – 3' in the primer taught by Sommer is 100% identical to nucleotides 909-912 of SEQ ID NO: 38.

In addition, **Claim 1** is drawn to an isolated nucleic acid molecule comprising a polyucleotide having a nucleotide sequence at least 95% identical to a sequence selected from a defined group which include a polynucleotide encoding a polypeptide domain/epitope of SEQ ID NO: 83 or a polypeptide domain/epitope encoded by the CDNA sequence included in ATCC Deposit No: 209563, which is hybridizable to SEQ ID NO:38.

Sommer et al. teach an isolated nucleic acid molecule comprising a polyucleotide (i.e. primer : 5'-TCGCAACATCGCAGCTA –3', see first primer listed Table I) having (i.e. comprising) a nucleotide sequence (5' – GCTA – 3') that is at least 95% identical to a polynucleotide encoding a polypeptide domain of SEQ ID NO: 83. Note, for example, that the sequence 5' – GCTA – 3' in the primer taught by Sommer is 100% identical to nucleotides 909-912 of SEQ ID NO: 38.

Finally, **Claim 1** is drawn to an isolated nucleic acid molecule comprising a polyucleotide having a nucleotide sequence at least 95% identical to a sequence selected from a defined group which include a polyucleotide capable of hybridizing under stringent conditions to any one of the polynucleotides specified in (a)-(h), wherein said polynucleotide does not hybridize under stringent conditions to a nucleic acid molecule having a nucleotide sequence of only A residues or of only T residues.

Sommer et al. teach an isolated nucleic acid molecule comprising a polyucleotide (i.e. primer : 5'-TCGCAACATCGCAGCTA –3', see first primer listed Table I) having (i.e. comprising) a nucleotide sequence (5' – GCTA – 3') that is at least 95% identical to a polynucleotide capable of hybridizing under stringent conditions to any one of the polynucleotides specified in (a)-(h), wherein said polynucleotide

does not hybridize under stringent conditions to a nucleic acid molecule having a nucleotide sequence of only A residues or of only T residues.

Note, for example, that the sequence (i.e.primer : 5'- TCGCAACATCGCAGCTA –3', a 17-mer) will hybridize to (i.e. prime the amplification of) 5' - TAGC- 3' at nucleotides 174-177 of SEQ ID NO:38. Sommer et al. teach that for primers with a length of 17-20 nucleotides all that is needed for priming of a target (i.e. hybridization thereto) is 3 homologous nucleotides at its 3' end of the primer. Admittedly, the priming will not be specific but the claim does not require that the polynucleotide claimed be homologous to SEQ ID NO:38 throughout its entire length.

Claim 33 is drawn to an isolated nucleic acid molecule comprising a first polyucleotide 95% or more identical to a second polynucleotide selected from a defined group which includes a polynucleotide encoding amino acid residues 1-88 of SEQ ID NO: 83 or a polynucleotide encoding amino acid residues 2-88 of SEQ ID NO: 83 or a polynucleotide encoding amino acid residues 22-88 of SEQ ID NO: 83.

Sommer et al. teach an isolated nucleic acid molecule (i.e. primer : 5'- TCGCAACATCGCAGCTA –3', see first primer listed Table I) comprising a first polyucleotide (i.e. 5' – GCTA – 3') 95% or more identical to a second polynucleotide selected from a defined group which includes a polynucleotide encoding amino acid residues 1-88 of SEQ ID NO: 83 or a polynucleotide encoding amino acid residues 2-88 of SEQ ID NO: 83 or a polynucleotide encoding amino acid residues 22-88 of SEQ ID NO: 83. Note, for example, that the sequence 5' – GCTA – 3' in the primer taught by Sommer is 100% identical (i.e. 95% or more) to nucleotides 909-912 of SEQ ID NO: 38 (i.e. a second polynucleotide encoding amino acid residues 1-88 of SEQ ID NO: 83 or a second polynucleotide encoding amino acid residues 2-88 of SEQ ID NO: 83 or a second polynucleotide encoding amino acid residues 22-88 of SEQ ID NO: 83.

Claim 37 is drawn to an isolated nucleic acid molecule comprising a first polyucleotide 95% or more identical to a second polynucleotide selected from a defined group which includes a polyucleotide encoding the amino acid sequence of the full-length polypeptide, which amino acid sequence is encoded by the IIMADS4I CDNA contained in ATCC Deposit No. 209563; and (b) a polynucleotide encoding the amino acid sequence of the secreted polypeptide, which amino acid sequence is encoded by the HMADS4I CDNA contained in ATCC Deposit No. 209563.

Sommer et al. teach an isolated nucleic acid molecule (i.e. primer : 5'- TCGCAACATCGCAGCTA –3', see first primer listed Table I) comprising a first polyucleotide (i.e. 5' – GCTA – 3') 95% or more identical to a second polynucleotide encoding the amino acid sequence of the full-length polypeptide,

which amino acid sequence is encoded by the IIMADS4I CDNA contained in ATCC Deposit No. 209563 or a polynucleotide encoding the amino acid sequence of the secreted polypeptide, which amino acid sequence is encoded by the HMADS4I CDNA contained in ATCC Deposit No. 209563. Note, for example, that the sequence 5' – GCTA – 3' in the primer taught by Sommer is 100% identical to nucleotides 909-912 of SEQ ID NO: 38.

10. **Claim(s) 1, 33, 37, 40-43** is/are rejected under 35 U.S.C. 102(e) as being anticipated by Jacobs et al. [US20020173635 (2002).

Jacobs et al. teach a clone (i.e. EM42) which comprises a sequence identical to nucleotides 22-473 of SEQ ID NO:38. See the attached sequence alignment.

Conclusion

11. **Claim(s) 1,14, 25-51** is/are rejected and/or objected to for the reason(s) set forth above.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ethan Whisenant, Ph.D. whose telephone number is (703) 308-6567. The examiner can normally be reached Monday-Friday from 8:30AM -5:30PM EST or any time via voice mail. If repeated attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached at (703) 308-1152.

The fax number for this Examiner is (703) 746-8465. Before faxing any papers please inform the examiner to avoid lost papers. Please note that the faxing of papers must conform with the Notice to Comply published in the Official Gazette, 1096 OG 30 (November 15, 1989). Any inquiry of a general nature or relating to the status of this application should be directed to the group receptionist whose telephone number is (703) 308-0196.

♦Please note that the USPTO is scheduled to begin relocating to its new home in Alexandria, VA very soon (JAN 04'). As a result, the examiner's telephone and desktop FAX numbers will be changing. The new telephone and desktop FAX numbers for Ethan Whisenant, Ph.D. are/will be as shown below:

New Telephone number : (571) 272-0754
New FAX number : (571) 273-0754.

ETHAN WHISENANT
PRIMARY EXAMINER
Art Unit 1634